

WE CLAIM:

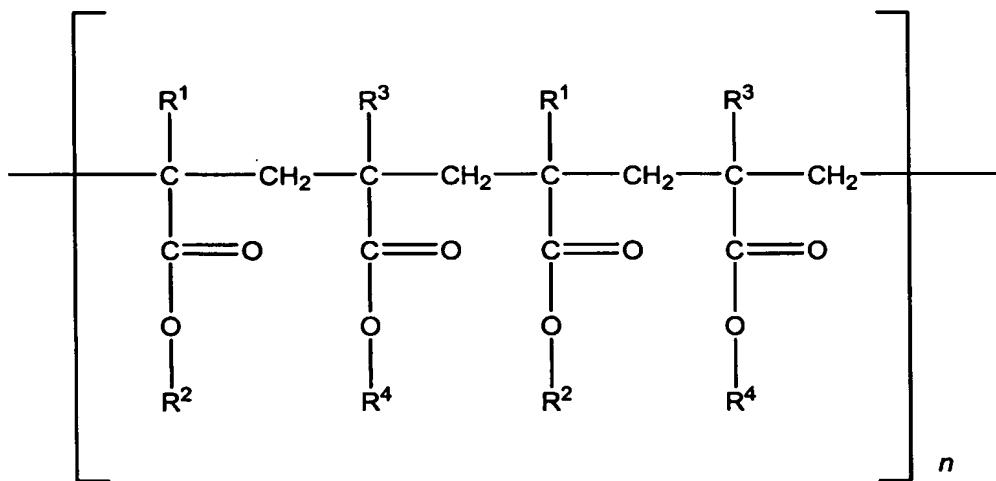
- 1 1. A taste-masked pharmaceutical dosage form comprising one or more drugs and
2 one or more cationic polymers synthesized from dimethylaminoethyl methacrylate
3 and neutral methacrylic acid esters, wherein the wt/wt ratio of the drug to polymer
4 is less than about one to two.
- 1 2. The taste masked pharmaceutical dosage form according to claim 1 wherein the
2 wt/wt ratio of the drug to polymer is less than approximately 1:1.7.
- 1 3. The taste masked pharmaceutical dosage form according to claim 1 wherein the
2 wt/wt ratio of the drug to polymer is less than approximately 1:1.5.
- 1 4. The taste masked pharmaceutical dosage form according to claim 1 wherein the
2 drug comprises one or more of H₂ receptor antagonists, antibiotics, analgesics,
3 cardiovascular agents, peptides or proteins, hormones, anti-migraine agents, anti-
4 coagulant agents, anti-emetic agents, anti-hypertensive agents, narcotic
5 antagonists, chelating agents, anti-anginal agents, chemotherapeutic agents,
6 sedatives, anti-neoplastics, prostaglandins, drugs for erectile dysfunction, drugs
7 acting on central nervous system, anti-diarrhoeal and anti-diuretic agents.
- 1 5. The taste masked pharmaceutical dosage form according to claim 1 wherein the
2 drug comprises one or more of nizatidine, cimetidine, ranitidine, famotidine,
3 roxatidine, etinidine, lupitidine, nifentidine, niperitone, sulfotidine, tuvatinidine,
4 zaltidine, erythromycin, penicillin, ampicillin, roxithromycin, clarithromycin,
5 psyllium, ciprofloxacin, theophylline, nifedipine, prednisone, prednisolone,
6 ketoprofen, acetaminophen, ibuprofen, dexibuprofen lysinate, flurbiprofen,
7 naproxen, codeine, morphine, sodium diclofenac, acetylsalicylic acid, caffeine,
8 pseudoephedrine, phenylpropanolamine, diphenhydramine, chlorpheniramine,
9 dextromethorphan, berberine, mefenamic acid, flufenamic acid, astemizole,
10 terfenadine, phenytoin, guiafenesin, N-acetylprocainamide HCl and
11 pharmaceutically acceptable salts or derivatives thereof.
- 1 6. The taste masked pharmaceutical dosage form according to claim 1 wherein the
2 drug comprises one more unpleasant tasting drugs.

1 7. The taste masked pharmaceutical dosage form according to claim 1 wherein the
2 drug comprises a low dose drug.

1 8. The taste masked pharmaceutical dosage form according to claim 7 wherein the
2 low dose drug comprises one or more of enalapril, lorazepam, zolmitriptan,
3 domperidone, selegiline, ondansetron, mirtazepine, hyosyamine sulphate,
4 risperidone, citalopram, olanzapine, rizatriptan, piroxicam, desloratadine,
5 cetirizine, loperamide, sildenafil, topiramate, and pharmaceutically acceptable salts
6 or derivatives thereof.

1 9. The taste masked pharmaceutical dosage form according to claim 1 wherein the
2 cationic polymer includes a dimethylaminoethyl group.

1 10. The taste masked pharmaceutical dosage form according to claim 1 wherein the
2 cationic polymer has the following formula:



3 where: $R^1 = R^3 = CH_3$
4
5 $R^2 = CH_2CH_2N(CH_3)_2$
6 $R^4 = CH_3, C_4H_9.$

1 11. The taste masked pharmaceutical dosage form according to claim 1 wherein the
2 cationic polymer comprises a polymers commercially available as Eudragit®.

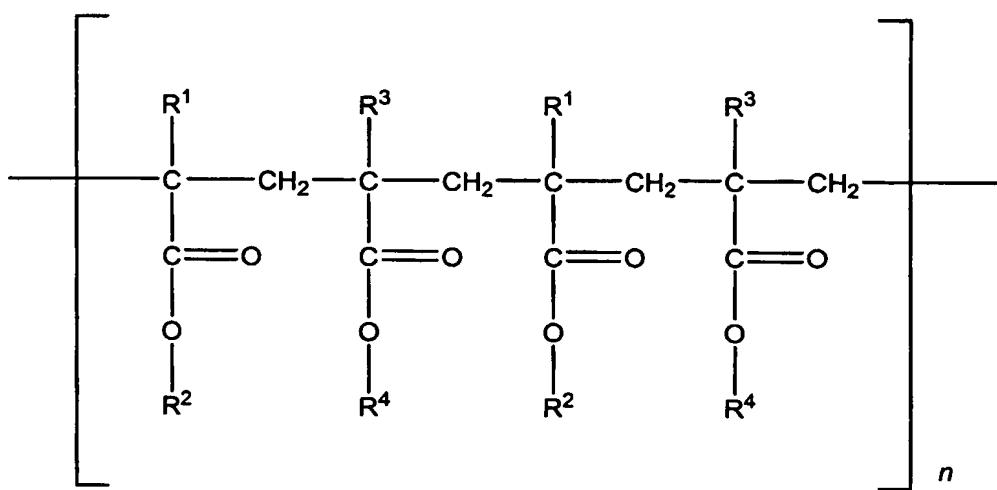
1 12. The taste masked pharmaceutical dosage form according to claim 11 wherein the
2 Eudragit® comprises one or both of Eudragit® E-100 and Eudragit® EPO.

- 1 13. The taste masked pharmaceutical dosage form according to claim 12 wherein the
- 2 Eudragit® comprises Eudragit® E-100.
- 1 14. The taste masked pharmaceutical dosage form according to claim 12 wherein the
- 2 Eudragit® comprises Eudragit® EPO.
- 1 15. The taste masked pharmaceutical dosage form according to claim 1 wherein the
- 2 dosage form further comprises other additives.
- 1 16. The taste masked pharmaceutical dosage form according to claim 15 wherein the
- 2 additives comprise one or more of cellulose ester, talc, magnesium stearate and
- 3 pigments.
- 1 17. The taste masked pharmaceutical dosage form according to claim 16 wherein the
- 2 cellulose ester comprises one or more of cellulose acetate, cellulose acetate
- 3 butyrate, cellulose triacetate, ethyl cellulose and mixtures thereof.
- 1 18. The taste masked pharmaceutical dosage form according to claim 1 wherein a drug
- 2 solution/dispersion is coated onto a water soluble or insoluble inert core.
- 1 19. The taste masked pharmaceutical dosage form according to claim 18 wherein the
- 2 water soluble or insoluble inert core comprises one or more of directly
- 3 compressible dibasic calcium phosphate, directly compressible sugar,
- 4 microcrystalline cellulose, and nonpareil sugar seeds.
- 1 20. The taste masked pharmaceutical dosage form according to claim 19 wherein the
- 2 inert core comprises directly compressible mannitol.
- 1 21. The taste masked pharmaceutical dosage form according to claim 18 wherein the
- 2 inert core has a particle size greater than about 100 microns.
- 1 22. The taste masked pharmaceutical dosage form according to claim 1 wherein the
- 2 dosage form is selected from the group consisting of sprinkles, chewable tablets,
- 3 mouth dissolving tablets, water dispersible tablets, effervescent tablets and
- 4 suspensions.

5 trichloroethylene, tetrachloroethylene, ethyl acetate, n-butyl acetate, propylene
 6 glycol acetate, toluene and mixtures thereof.

1 31. The process according to claim 25 wherein the cationic polymer includes a
 2 dimethylaminoethyl group.

1 32. The process according to claim 25 wherein the cationic polymer has the following
 2 formula:



3 where: $R^1 = R^3 = CH_3$
 4 $R^2 = CH_2CH_2N(CH_3)_2$
 5 $R^4 = CH_3, C_4H_9.$

1 33. The process according to claim 25 wherein the cationic polymer comprises a
 2 polymer commercially available as Eudragit®.

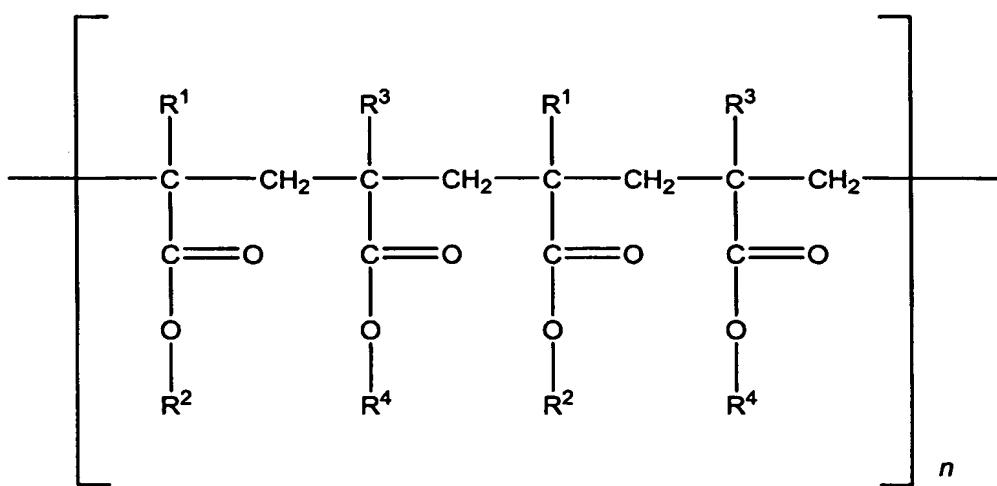
1 34. The process according to claim 25 wherein the Eudragit® comprises one or both of
 2 Eudragit® E-100 and Eudragit® EPO.

1 35. A taste masked pharmaceutical dosage form comprising:
 2 an inert core;
 3 one or more drugs; and
 4 one or more cationic polymers,
 5 wherein one or more cationic polymers are synthesized from dimethylaminoethyl
 6 methacrylate and neutral methacrylic acid esters, the one or more drugs and the

7 one or more cationic polymers form a layer around the inert core, and the wt/wt
 8 ratio of the drug to polymer in the dosage form is less than about one to two.

1 36. The taste masked pharmaceutical dosage form according to claim 35 wherein the
 2 cationic polymer includes a dimethylaminoethyl group.

1 37. The taste masked pharmaceutical dosage form according to claim 35 wherein the
 2 cationic polymer has the following formula:



3 where: $R^1 = R^3 = CH_3$

5 $R^2 = CH_2CH_2N(CH_3)_2$

6 $R^4 = CH_3, C_4H_9.$

1 38. The taste masked pharmaceutical dosage form according to claim 35 wherein the
 2 cationic polymer comprises a polymer commercially available as Eudragit®.

1 39. The taste masked pharmaceutical dosage form according to claim 35 wherein the
 2 Eudragit® comprises one or both of Eudragit® E-100 and Eudragit® EPO.

1 40. The taste masked pharmaceutical dosage form according to claim 35 wherein the
 2 inert core comprises one or more of directly compressible dibasic calcium
 3 phosphate, directly compressible sugar, microcrystalline cellulose, and nonpareil
 4 sugar seeds.